

K061034

JUN 23 2006

**TAB 3**

## 510(K) SUMMARY OF SAFETY & EFFECTIVENESS

<b>Official Contact</b>	<p>Zita A. Yurko  Manager, Regulatory Affairs  Respironics, Inc.  1001 Murry Ridge Lane  Murrysville, PA 15668</p> <p>724-387-4120  724-387-4206 (fax)  Email: Zita.Yurko@Respironics.com</p>
<b>Classification Reference</b>	21 CFR 868.5905
<b>Product Code</b>	BZD – Non-Continuous ventilator
<b>Common/Usual Name</b>	CPAP System
<b>Proprietary Name</b>	Respironics BiPAP Plus M Series Bi-level System
<b>Predicate Device(s)</b>	<p>Respironics REMstar Pro M Series CPAP System (K052110)</p> <p>Respironics BiPAP Pro 2 Bi-level System (K43607)</p>
<b>Reason for submission</b>	Modified design.

## Substantial Equivalence

The modified device has the following similarities to the previously cleared predicate device:

- ☐ Same intended use.
- ☐ Same operating principle.
- ☐ Same technology.
- ☐ Same manufacturing process.

Design verification tests were performed on the Respironics BiPAP Plus M Series Bi-level System as a result of the risk analysis and product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the device described in this submission is substantially equivalent to the predicate devices.

The modified device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices," May 2006.

## Intended Use

The Respironics BiPAP Plus M Series Bi-level System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30kg. For use in the home or hospital/institutional environment.

## Device Description

The Respironics BiPAP Plus M Series Bi-level System is a smaller and lighter microprocessor controlled blower based positive pressure system with integrated heated humidifier. The device platform and fundamental technology is based on the Respironics REMstar Pro M Series CPAP System (K052110). The BiPAP Plus M Series Bi-level System includes the flex therapy feature cleared in K043607, which provides the patient with additional comfort by easing the transition from the end of inspiration to the beginning of exhalation. Like its predicate, the BiPAP Plus M Series Bi-level System is intended for use with a patient circuit that is used to connect the device to the patient interface device (mask). A typical patient circuit consists of a six-foot disposable or reusable smooth lumen 22mm tubing, an exhalation device, and a patient interface device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 23 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Respironics, Incorporated  
C/O Ms. Zita A. Yurko  
Manager, Regulatory Affairs  
Sleep & Home Respiratory Group  
1001 Murry Ridge Lane  
Murrysville, Pennsylvania 15668

Re: K061034

Trade/Device Name: BiPAP Plus M-Series Bi-Level System  
Regulation Number: 868.5905  
Regulation Name: Noncontinuous Ventilator (IPPB)  
Regulatory Class: II  
Product Code: BZD  
Dated: May 25, 2006  
Received: May 26, 2006

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K061034

Device Name: BiPAP Plus M-Series Bi-level System

Indications For Use:

### *Intended Use/Indications for Use*

The Respirationics BiPAP Plus M Series Bi-level System delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea in spontaneously breathing patients weighing over 30kg.

### *Environment of Use/Patient Population*

For use in the home or hospital/institutional environment.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

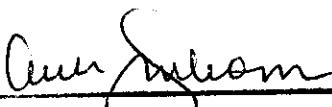
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Signature Sign-Off)  
Division of Anesthesiology, General Hospital,  
Division Control, Dental Devices  
(5) Number:   K061034